

Serial No.: 10/541,823
Atty. Docket No.: P70681US0

REMARKS

The Office Action mailed September 12, 2006, has been carefully reviewed and, by this Amendment, Applicants have canceled claims 19-36 and added claims 37-51. Claims 37-51 are pending in the application. Claims 37, 48, 50 and 51 are independent.

As an initial matter, Applicants have corrected informalities noted in the abstract.

The Examiner rejected claims 19-36 under 35 U.S.C. 102(b) as being anticipated by WO 98/53771 to Nielsen et al. ("Nielsen"). Under 35 U.S.C. 103(a), the Examiner rejected claim 26 8 as being unpatentable over Nielsen.

With the cancellation of claims 19-36 herein, the rejections are technically moot. However, with respect to new claims 37-51, Applicants provide the following remarks.

As set forth in new claims 37 and 48, the present invention is directed to an adhesive wafer or sealing member having an inner rim defining a hole for accommodating a stoma, a first adhesive surface to adhere to the skin and a second surface facing away from the user. The part of the second surface surrounding the hole is provided with a hydrophobic adhesive which is compatible with the first adhesive surface. The wafer or sealing member is

Serial No.: 10/541,823
Atty. Docket No.: P70681US0

configured to allow the stoma-accommodating hole to be enlarged by rolling up the inner rim of the hole to form a torus. The torus is locked in this rolled up position through the adherence of the first adhesive surface and the hydrophobic adhesive on the second surface. The hydrophobic adhesive ensures that the torus will not unroll even when the first adhesive surface is exposed to moisture. This is important because the first adhesive surface is typically a moisture absorbing adhesive and therefore susceptible to losing its adhesive tack in the presence of moisture. Without the hydrophobic adhesive on the second surface, this loss of adhesive tack will allow the torus to unroll, creating a risk of injury or constriction of the stoma. This structure in which a second, hydrophobic, adhesive is provided on the side of the sealing member opposite the skin-adhering side is not shown by Nielsen.

Nielsen discloses an ostomy appliance having an adhesive wafer and a separate sealing member for sealing around the stoma. The sealing member includes an adhesive layer 7 which is covered on the non-skin-facing surface with a film layer 14. The film layer 14 is not adhesive but instead is intended to be non-tacky (see page 8, lines 12-13; page 13, line 20; page 14, lines 9-11). In order to connect the sealing member to the adhesive wafer 2, a

Serial No.: 10/541,823
Atty. Docket No.: P70681US0

flange 8, 16 is attached to the film layer 14 and to the adhesive wafer, and serves as a bridge between the two components.

As in the present invention, the portion of the sealing member surrounding the stoma may be rolled up to form a torus for adapting to the size of the stoma. However, contrary to the Examiner's statement that the flange 8, 16 aids in locking the torus in the rolled up position, in fact the flange has no influence on the rolling up and locking of the torus in the rolled up position. Even if the adhesive layer 13 of the receiving member 4 is brought into contact with the flange 8, 16, it is not in direct contact with the adhesive 7 of the sealing member.

Further with respect to the locking of the torus, in Nielsen the torus is held in the rolled up position by attachment of the first adhesive surface 7 to the non-adhesive second surface 14. While not identified with a reference numeral in Figure 7 of Nielsen, this non-adhesive second surface 14 is represented by the unhatched layer shown immediately on top of the layer 7. Significantly, the first adhesive surface formed by the mass 7 is usually a moisture-absorbing adhesive such as, for example, a hydrocolloid adhesive. As explained above, such adhesives may lose their adhesive tack when exposed to moisture. This is confirmed in

Serial No.: 10/541,823
Atty. Docket No.: P70681US0

Nielsen which teaches that, when the torus of Nielsen is exposed to moisture from the stoma, the adhesive holding the torus may lose its tack to the film surface 14 of the second surface, allowing the torus to unroll and revert to its original flat configuration (see page 12, lines 3-9).

The present invention, unlike Nielsen, prevents unrolling by providing a second hydrophobic adhesive on the second surface. With the two adhesives being in contact with one another when the torus is rolled up, the chances of the torus unrolling are greatly reduced for, even if the first adhesive is moistened and loses its tack, the second hydrophobic adhesive will still be effective in keeping the torus securely in the correct, rolled position.

Hence, Applicants request reconsideration on the basis of the new claims and the foregoing remarks and also in view of the Examiner's expressed interpretation of what Nielsen teaches.

The Examiner states that the wafer 2 of Nielsen has a "first adhesive surface" for securing the appliance to the user's skin and a second adhesive surface covered with sheet 16. The indicated use for securing to the skin suggests that the "first adhesive surface" to which the Examiner is referring is the bottom surface of wafer 2.

Contrary to this interpretation, however, the Examiner later in the same paragraph identifies the "first adhesive surface"

Serial No.: 10/541,823
Atty. Docket No.: P70681US0

as being adhesive 13. However, since adhesive 13 attaches the flange 12 of the bag to the flange 11 of the body side member (see page 6, lines 12-14), it is clearly not a surface used to secure the appliance to the skin.

Next, the Examiner states that the wafer 2 is integral with sealing member 5 and that this "[s]ealing member 5 integral with wafer 2 comprises a hydrophobic adhesive". Applicants cannot find support or suggestion for this statement in Nielsen.

First, Nielsen is primarily directed to a sealing member that can be exchanged independently of the body side member including wafer 2 (see page 6, lines 15-25). While Nielsen mentions that in an alternative embodiment the wafer and sealing member can be integrated into one unit, this is not what is shown in Figures 4 and 6-9. Rather, Figures 4, 6 and 7 show an adhesive mass 7 with a backing 14 thereon (incorrectly identified with reference numeral 5 in Figure 4; the lead line from reference numeral 5 in Figure 4 should have had an arrow on the end indicating the entire sealing member including the mass 7 and the backing 14). Rather than being integrated with the sealing member, as maintained by the Examiner, in fact the wafer is simply not shown in Figures 4 or 6-9, but is shown only in Figures 1 and 5.

Second, Nielsen does not teach that in either the exchangeable sealing member embodiments of Figures 4-9, or in the

Serial No.: 10/541,823
Atty. Docket No.: P70681US0

"alternative" single unit embodiment mentioned on page 8, that the sealing member includes a hydrophobic adhesive compatible with the "first adhesive surface". As explained above, the "first adhesive surface" as claimed herein cannot be adhesive 13, as cited by the Examiner in connection with the hydrophobic adhesive limitation, since adhesive 13 does not contact the skin. Instead, the "first adhesive surface" must be the lower surface of adhesive mass 7. And Nielsen is silent with respect to any teaching of a hydrophobic adhesive compatible with the adhesive mass 7 as claimed by the present invention.

For at least the foregoing reasons, claims 37 and 48 are patentable over Nielsen. Claims 50 and 51 are also patentable as being directed to methods of applying a sealing member having a hydrophobic adhesive in combination with a moisture-absorbing adhesive on opposite sides of the sealing member for locking a torus in the rolled position.

Claims 38-47 and 49 are in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned

Serial No.: 10/541,823
Atty. Docket No.: P70681US0

attorney so that the present application can receive an early
Notice of Allowance.

Respectfully submitted,

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